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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,650	05/09/2006	David B. Weiner	UPAP0020-100	2255

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EXAMINER	
SHEN, WU CHENG WINSTON	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,650	WEINER ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6,8,9,11,14-17,19-29,35,36,38 and 52-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-6,8,9,11,14-17,19-29,35,36,38 and 52-54 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary claim amendment dated 12/13/2005 has been received. Claims 1-6, 8, 11, 14-17, 19-29, 35, 36, 38, 52, and 53 are amended. Claim 54 is added as a new claim. Claims 1-6, 8, 9, 11, 14-17, 19-29, 35, 36, 38, and 52-54 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 8, 9, 11, 14-17, 19-23, 29, 38, and 54 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a non-immunogenic fusion protein that comprises a *non-IL-15 signal peptide fused to IL-15 protein* or a functional fragment thereof, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

II. Claims 1-6, 8, 9, 11, 14-17, 19-23, 29, 38, and 54 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of: a

nucleotide sequence that encodes *CD40L* or a functional fragment thereof, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

III. Claims 1-6, 8, 9, 11, 14-17, 19-23, 29, 38, and 54 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a *non-IgE protein sequences fused to a IgE signal peptide* that is from the same species as the non-IgE protein, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

IV. Claim 24 (in part), drawn to a live attenuated pathogen comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a non-immunogenic fusion protein that comprises a non-IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

V. Claims 24 (in part), drawn to a live attenuated pathogen comprising a nucleic acid sequence consisting of: a nucleotide sequence that encodes CD40L or a functional fragment thereof, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

VI. Claim 24 (in part), drawn to a live attenuated pathogen comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to a IgE signal peptide that is from the same species as the non-IgE protein, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid.

VII. Claims 25-28 (each in part), drawn to a fusion protein consisting of: a non-immunogenic fusion protein that comprises a non-IL-15 signal sequence linked to an IL-15 protein sequence.

VIII. Claims 25-28 (each in part), drawn to a fusion protein consisting of: a fusion protein comprising an IRE signal peptide linked to non-IgE protein wherein the IgE signal peptide and the non-IgE protein are derived from the same species of animal.

IX. Claims 35 (in part), drawn to a method of modulating an immune response in an individual comprising administering to said individual a composition consisting of: a composition comprising a nucleic acid molecule that comprises nucleic acid sequence that encodes a non-immunogenic fusion protein that comprises a non-IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof.

X. Claims 35 (in part), drawn to a method of modulating an immune response in an individual comprising administering to said individual a composition consisting of: a composition comprising a nucleic acid molecule that comprises a nucleotide sequence that encodes CD40L or a functional fragment thereof.

XI. Claims 36 (in part), drawn to a method of inducing an immune response in an individual against an immunogen comprising administering to said individual a composition consisting of: a composition comprising a nucleic acid molecule that comprises a nucleic acid sequence that encodes a non-immunogenic fusion protein that comprises a non- IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof, and further comprises a nucleic acid sequence that encodes an immunogen.

XII. Claims 36 (in part), drawn to a method of inducing an immune response in an individual against an immunogen comprising administering to said individual a composition consisting of: a composition comprising a nucleic acid molecule that comprises a nucleic acid sequence that encodes CD40L or a functional fragment thereof, and further comprises a nucleic acid sequence that encodes an immunogen.

XIII. Claims 52, drawn to an in vitro cell culture that comprises cells that comprise a nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the nucleic acid sequence is operably linked to regulatory elements required for expression in said cells.

XIV. Claims 53, drawn to A method of preparing a non-IgE protein comprising culturing cells that comprise cells that comprises cells that comprise a nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the

nucleic acid sequence is operably linked to regulatory elements required for expression in said cells under condition necessary for fusion protein expression for a period sufficient for said cells to express said fusion protein.

3. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see

MPEP § 1850. In this case, the claims encompass multiple products and methods. Applicant's claims encompass multiple inventions, multiple products and multiple methods, and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups is a nucleic acid or a protein encoded by a nucleic acid that can be used for modulation of an immune response. However, this common technical feature cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art. **Armitage et al.** taught the identification and cloning of the cytokine IL-15 and demonstrated that IL-15 costimulates B cell proliferation and IL-15 induced Ig secretion in the presence of CD40L (See Figures 1, 4, Armitage et al., IL-15 has stimulatory activity for the induction of B cell proliferation and differentiation. *J Immunol.* 154(2):483-90, 1995).

4. Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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